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<p>(21) International Application Number: PCT/GR98/00026 (22) International Filing Date: 22 October 1998 (22.10.98) (30) Priority Data: 980100384 19 October 1998 (19.10.98) GR (71)(72) Applicants and Inventors: DIMITRIOU, K., Vasilios [GR/GR]; 9 Chrisippou Street, GR-116 31 Athens (GR). VOYAGIS, S., Gregorios [GR/GR]; 19 Kallistratou Street, GR-157 72 Athens (GR).</p>		<p>(81) Designated States: AU, CA, JP, US, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published With international search report. With amended claims.</p>
<p>(54) Title: DEVICE FOR GUIDED TRACHEAL INTUBATION</p> <div data-bbox="406 1113 1201 1344"><p>2 3 10a 1 4 10 10b 5 6 7 8 9</p></div> <p>(57) Abstract</p> <p>Device for guided tracheal intubation through the intubating laryngeal mask airway to facilitate lung ventilation in unconscious patients, comprising a completely flexible thin tube (1), a bulb of adequate brightness (2) fixed with atoxic glue and silicone (3), a 15-mm concentric adaptor (5), two leads (4) ending in a power connector (6) and an extension (7) ending in a battery (8) with a power switch (9). The device is inserted into the lumen of the tracheal tube (10) in such a way that the bulb protrudes from the distal end of the tracheal tube (10a) and changes the conventional blind technique of tracheal intubation through the intubating laryngeal mask airway, from blind to guided, by using the transillumination of the light through the soft tissues of the human body.</p>		

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Title of the inventionDEVICE FOR GUIDED TRACHEAL INTUBATIONField of the Invention

5 The present invention relates to a device for guided tracheal intubation without the use of laryngoscope in unconscious patients.

Background of the Invention

10 The classical method of orotracheal intubation is carried out under direct laryngoscopy [1]. The laryngeal mask airway has a role in the management of difficult airway as an aid to orotracheal intubation and has been widely used in the management of the adult and paediatric difficult airway since 1983 [2-5].

15 The conventional laryngeal mask airway has been introduced in the anaesthetic practice since 1981 and is commercially available since 1988 [6]. The intubating laryngeal mask airway has been introduced in the anaesthetic practice since 1995 [7]. The intubating laryngeal mask airway is a modification of the conventional laryngeal mask airway and consists of an anatomically curved (90°) short, wide bore, stainless steel tube sheathed in silicone which is bonded to a laryngeal mask airway and a guiding handle [8]. It has a single moveable aperture bar in order to elevate epiglottis, a guiding ramp and can accommodate an 8 mm tracheal tube. The most common technique of orotracheal intubation through the laryngeal mask airway or the intubating laryngeal mask airway is blind, since direct laryngoscopy is not used and the tracheal tube is advanced to trachea blindly through the laryngeal mask airway or the intubating laryngeal mask airway [1,3-5,7-9]. The success rate of blind orotracheal intubation through the conventional laryngeal mask airway is 30-90% [3-5], while through the intubating laryngeal mask airway this is improved to 70-99% [7-9]. The disadvantages of any blind technique are that they may be time consuming, misplacement may result in trauma and there is a risk of accidental oesophageal intubation [8]. It has to be underlined that in the most recent study of the manufacturer of the intubating laryngeal mask airway and his most experienced colleagues, blind orotracheal intubation was succeeded at the first attempt in only 50% (75/150) of

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patients, whereas 19% (28/150) required one blind adjusting manoeuvre and 30% (46/150) required 2-4 blind adjusting manoeuvres and 3-5 intubating attempts [8]. Each intubating attempt is defined as a forward and backward movement of the tracheal tube through the intubating laryngeal mask airway. As a result of the above
5 blind adjusting manoeuvres is the potential risk of airway trauma, haemodynamic instability as well as hypoxaemia due to delayed airway management.

The lighted stylet has been used to facilitate orotracheal intubation either in the anaesthesia or in the emergency medicine, since the decade of "70s [1,10]. It is consisted of a battery handle and a copper stylet covered in plastic and there is a bulb
10 on the distal end of the stylet. The stylet is inserted into the tube so that the distal bulb protrudes about 0.5 cm from the distal end of the tracheal tube. The tracheal tube and the stylet are then bent to an angle slightly more than 90° and are slid along the tongue to hook up the epiglottis and conduct the glottic opening. The position of the tracheal tube tip can be discerned readily by observing the transillumination of the soft tissues
15 of the neck. A bright glow in the midline at the level of the laryngeal prominence indicates correct placement. Following the correct placement, the stylet is held in place and the tracheal tube is advanced off the stylet distally to the proper depth. Care must be taken not to pull back on the stylet prior to advancing the tracheal tube into the trachea [10]. An improved version of the lighted stylet is the «Trachlight», that also
20 consists of a handle, a metal stylet covered with plastic and a bulb at its distal end [11]. Right and left pyriform fossa misplacement is seen lateral to the midline, while oesophageal misplacement results in a diffuse and subdued light, if any [10,11].

The disadvantages of orotracheal intubation facilitated with lighted stylets are that they may be time consuming and misplacement may result in trauma. The
25 possibility of such misplacements (right lateral, left lateral or oesophageal) is high and consequently there is a potential risk of airway trauma, haemodynamic instability as well as hypoxaemia due to delayed airway management [1,10].

Even the most skilled anaesthesiologists may encounter what is commonly referred to as a «difficult» airway. This occurs in about 5% of all operating room
30 intubations, with an even higher incidence of inability to fully visualize the glottic opening [1,12,13]. The incidence level is significantly higher in other areas of hospital

and prehospital environment. Although, presurgical examination of the jaw, teeth, mouth opening and neck motion assists in gauging the degree of difficulty likely to be encountered at intubation, not all difficult intubations can be identified in advance [1,12,13]. There is always the unexpected difficult airway, discovered only at the time of intubation. In emergency situations, there is little if any time to perform an airway assessment prior to attempting intubation. Thus, all emergency tracheal intubations are considered «difficult» intubations. In such circumstances the above referred techniques [1-11] are indicated to be used, but the successful outcome can not be guaranteed and the possibility of serious complications is always present [1].

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Summary of the Invention

The subject invention is considered as a necessary supplement in the completion of orotracheal intubation through the intubating laryngeal mask airway. The basic principle of the subject invention is the transillumination of the light through the soft tissues of the human body. According to the above basic principle, the main purpose of the subject invention was to attach a bulb at the distal end of the tracheal tube, in order to be indicated, either the tracheal tube position in the laryngopharynx, or the route that the tracheal tube follows during its advancing procedure from the laryngopharynx to the trachea through the intubating laryngeal mask airway. Thereafter, the device of the subject invention changes the conventional technique of intubation, as it is suggested by the manufacturer of intubating laryngeal mask airway [7,8], from blind to guided.

The aims of the subject invention are: (a) decreased number of adjusting manoeuvres in the procedure of modified orotracheal intubation through the intubating laryngeal mask airway, (b) decreased number of failed attempts of advancing the tracheal tube to the trachea, (c) decreased overall duration of the procedure of intubation through the intubating laryngeal mask airway, (d) decreased risk of trauma in laryngopharynx, (e) decreased haemodynamic impact of the orotracheal intubation (cardiovascular instability: arterial hypertension, tachycardia, arrhythmias), (f) ease in learning and training orotracheal intubation through the intubating laryngeal mask airway by all non-anaesthetic personnel involved in airway management following a

short training program and (g) effective and fast orotracheal intubation, even in cases of difficult airway, whenever other conventional techniques either under direct laryngoscopy, or blindly through the intubating laryngeal mask airway have failed.

In one embodiment the subject invention, should be manufactured for single patient use thereby eliminating the requirement for cleaning, and most importantly eliminating the opportunity for cross contamination between patients. In a specific embodiment the subject invention can be disposable, sterilizable for reuse or enclosed within a disposable sheath for reuse without expensive sterilization.

10 Brief Description of the Drawings

FIGURE 1 shows the device of the subject invention.

FIGURE 2 shows the device of the subject invention after its placement in the lumen of the tracheal tube.

FIGURE 3 illustrates an intubating laryngeal mask airway in use in a patient; the device of the subject invention with the tracheal tube has been advanced in the lumen of intubating laryngeal mask airway; the distal end of the tracheal tube protrudes from the bowl of intubating laryngeal mask airway; the bulb of the subject invention is turned on; and the bright glow is transilluminated to the neck.

20 Detailed Disclosure of the Invention

The subject invention utilizes the transillumination of the light through the soft tissues of the human body as a guide for the successful insertion of the tracheal tube from the laryngopharynx to the trachea. The device of the subject invention can assist doctors and all non-anaesthetic personnel involved in airway management in properly introducing and confirming the position of the tracheal tube in the procedure of tracheal intubation without the usage of laryngoscopes, since the direct laryngoscopy is not necessary. Although, the device has application in «difficult» intubations, use in all intubations is suggested in the everyday practice. The device of the subject invention has application for intubating patients undergoing general, intravenous and local anaesthesia and in emergency situations. Thus, the device of the subject invention

can be used in surgical procedures as well as in intensive care units, emergency departments and the prehospital settings.

The subject invention incorporates aspects of both the blind technique used by intubating laryngeal mask airway and the guided technique that uses the indirect transcutaneous illumination of the trachea. The former achieves the placement of the tracheal tube up to the laryngopharynx and the latter achieves a quick and safe advancing of the tracheal tube from the laryngopharynx to the trachea.

Referring to Figures 1 and 2, the device of the subject invention consists of a thin plastic tube 1, which at its distal end comprises a bulb 2 of adequate brightness fixed with atoxic glue and silicone 3. Two leads 4 are running along the lumen of the thin plastic tube 1, ending in a power connector 6 and an extension 7 is starting from the power connector 6 ending in a battery 8 with a power switch 9. At the proximal end of the thin plastic tube 1, there is a 15-mm concentric adaptor 5 where the tracheal tube 10 is immobilized. The tracheal tube 10 is suggested to be flexible with reinforced wall, in order to avoid kinking. The maximum length of the thin plastic tube 1 may be up to 35 cm, while the maximum outer diameter may be up to 5 mm. The thin plastic tube 1 is flexible without any metallic component. In one embodiment the thin flexible tube 1 of the subject invention, should be manufactured, either from plastic, or from other materials (e.g. papier mâché) for single patient use thereby eliminating the requirement for cleaning and most importantly eliminating the opportunity for cross contamination between patients. In a second embodiment the thin flexible tube 1 should be armoured (spiral) with reinforced wall, avoiding kinking. In a specific embodiment the thin flexible tube 1 of the subject invention can be disposable, sterilizable for reuse or enclosed within a disposable sheath with a transparent end plate for reuse without expensive sterilization.

Referring to Figure 2, the device of the subject invention has been placed into the lumen of the tracheal tube 10 in such a way that the bulb 2 protrudes from the distal end of the tracheal tube 10a in a distance of 0.5 cm. Additionally, the figure 2 shows the fixing mechanism of the tracheal tube connector 10b to the adaptor 5 of the subject invention. The concentric adaptor 5 has a changeable fixing point, in order to be adjusted to the proper length of the tracheal tube 10, which is every time chosen.

Referring to Figure 3, the intubating laryngeal mask airway has been placed in the laryngopharynx of the patient. The anaesthesiologist 1 advances the tracheal tube 2 with the device of the subject invention in the metallic lumen 3 of the intubating laryngeal mask airway. When the distal end of the tracheal tube 4 protrudes into the bowl 5 of the intubating laryngeal mask airway about 2 cm, the bulb 6 is at the glottic opening. Then, the position of the tracheal tube tip can be discerned readily by observing the transillumination of the glow 7 to the soft tissues of the neck. A bright glow in the midline at the level of the laryngeal prominence indicates correct placement. In that case, the tracheal tube is advanced into the trachea and the device of the subject invention is pulled back. Right or left lateral glow indicates misplacement of the tracheal tube in the pyriform fossa, while oesophageal misplacement results in a diffuse and subdued light, if any. In these cases, by the aid of the handle of the intubating laryngeal mask airway 8, adjusting manoeuvres are carried out in order to achieve a redirection of the glow in the right position in the midline at the level of the laryngeal prominence.

The flexibility of the device of the subject invention facilitates its advancing in the lumen of the tracheal tube. Moreover, the device of the subject invention does not impede the insertion of the tracheal tube either in the curved (90°), stainless steel lumen of intubating laryngeal mask airway, or in the trachea. The latter means that after the identification of the glow in the midline at the level of the laryngeal prominence, the tracheal tube is inserted freely without any resistance.

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CLAIMS:

1. Device for guided tracheal intubation through the intubating laryngeal mask airway to facilitate lung ventilation in unconscious patients, comprising a completely flexible thin tube and a bulb of adequate brightness attached to the distal end of the thin tube, a 15-mm concentric adaptor at the proximal end of the thin tube, two leads running along the lumen of the thin tube ending in a power connector and an extension starting from the power connector ending in a battery with a power switch.
2. Device for guided tracheal intubation through the intubating laryngeal mask airway as claimed in claim 1, wherein the thin tube is plastic and completely flexible without any metallic component, with maximum length up to 35 cm and maximum outer diameter up to 5 mm.
3. Device for guided tracheal intubation through the intubating laryngeal mask airway as claimed in claim 1, wherein the bulb is fixed at the distal end of the thin plastic tube with atoxic glue and silicone.
4. Device for guided tracheal intubation through the intubating laryngeal mask airway as claimed in claim 1, wherein the concentric 15-mm adaptor has a changeable fixing point, in order to be adjusted to the proper length of the tracheal tube, which is every time chosen.
5. Device for guided tracheal intubation through the intubating laryngeal mask airway as claimed in any preceding claim, which is placed into the lumen of the tracheal tube in such a way that the bulb protrudes from the distal end of the tracheal tube in a distance of approximately 0.5 cm.

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6. Device for guided tracheal intubation through the intubating laryngeal mask airway as claimed in claim 5, which is placed into the lumen of the tracheal tube, in order to change the conventional blind technique of orotracheal intubation, from blind to guided, by using the transillumination of the light through the soft tissues of the human body.

7. Device for guided tracheal intubation as claimed in claim 2, wherein the thin plastic tube is disposable, sterilizable for reuse.

10 8. Device for guided tracheal intubation as claimed in claim 2, wherein the thin plastic tube further comprises a disposable sheath with a transparent end plate within which said thin plastic tube is inserted during use.

15 9. Device for guided tracheal intubation as claimed in claim 1, wherein the thin flexible tube should be manufactured from papier mâché or other flexible material.

10. Device for guided tracheal intubation as claimed in claim 1, wherein the thin flexible tube should have reinforced (spiral) wall, avoiding kinking.

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AMENDED CLAIMS

[received by the International Bureau on 12 October 1999 (12.10.99);
original claims 11,12 and 13 added; remaining claims unchanged (2 pages)]

- 5 order to change the conventional blind technique of orotracheal intubation, from blind
to guided, by using the transillumination of the light through the soft tissues of the
human body.
7. Device for guided tracheal intubation as claimed in claim 2, wherein the thin
10 plastic tube is disposable, sterilizable for reuse.
8. Device for guided tracheal intubation as claimed in claim 2, wherein the thin
plastic tube further comprises a disposable sheath with a transparent end plate within
which said thin plastic tube is inserted during use.
- 15 9. Device for guided tracheal intubation as claimed in claim 1, wherein the thin
flexible tube should be manufactured from papier mâché or other flexible material.
10. Device for guided tracheal intubation as claimed in claim 1, wherein the thin
20 flexible tube should have reinforced (spiral) wall, avoiding kinking.
11. Device for guided tracheal intubation through the intubating laryngeal mask as
claimed in claim 1, wherein the power connector is connected to the power source
without the extension.
- 25 12. Device for guided tracheal intubation through the intubating laryngeal mask
as claimed in claims 1 and 2, wherein the 15-mm concentric adaptor is removed, the
two leads at the proximal end of the thin flexible tube are connected immediately to a
power source and the thin flexible tube is running longitudinally into a small channel
30 into the wall of a flexible tracheal tube, ending at the distal end of the tracheal tube,
with reference to figure 3.

13. Device for guided tracheal intubation through the intubating laryngeal mask as claimed in claim 12, wherein the small channel is located along the outer wall of a flexible tracheal tube, ending at the distal end of the tracheal tube, with reference to figure 4.

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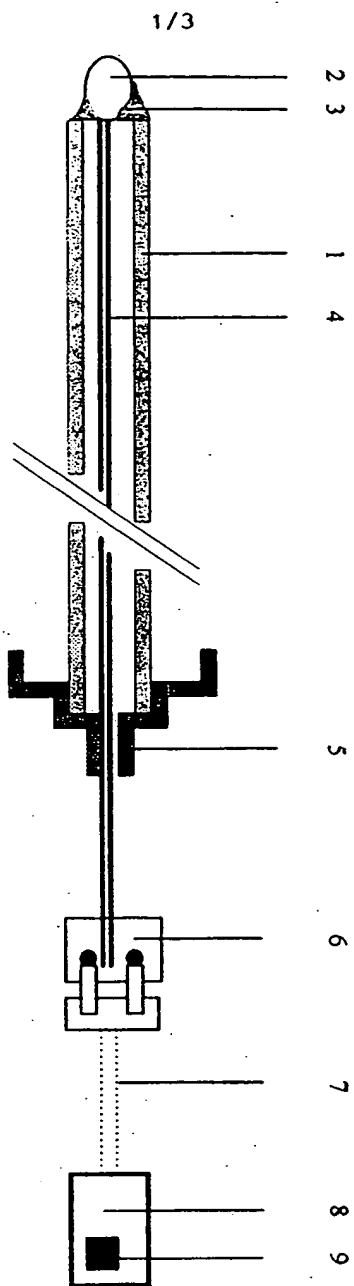


Fig 1.

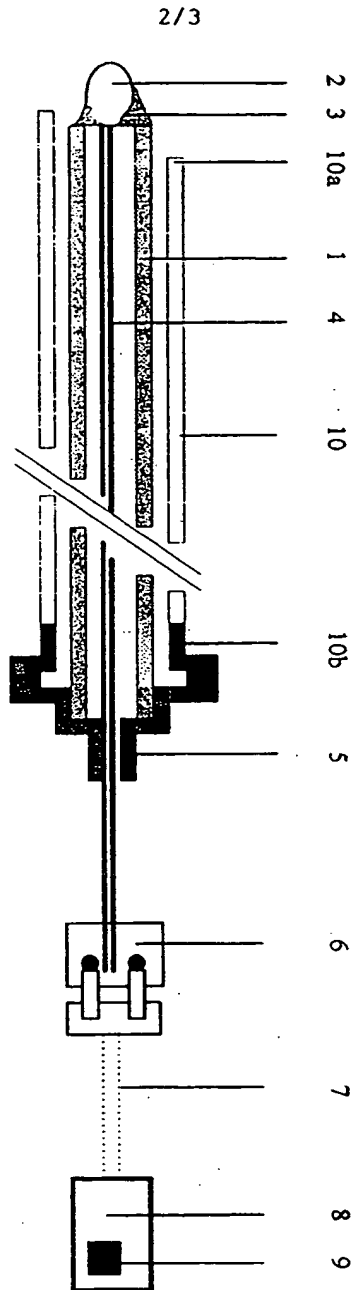


Fig. 2.

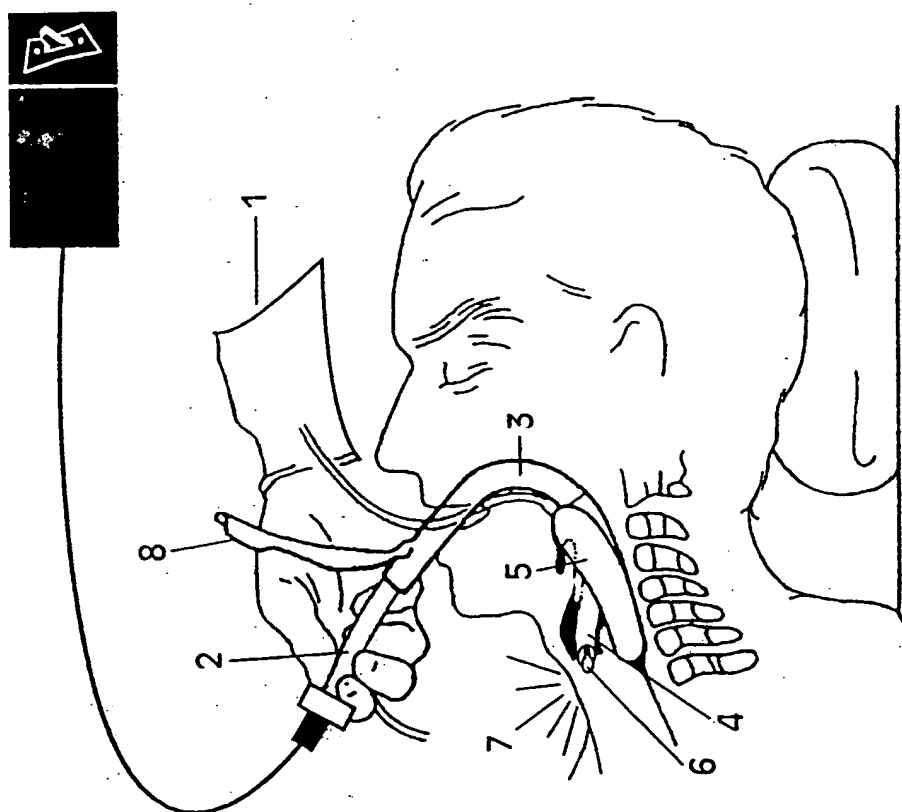


Fig 3

INTERNATIONAL SEARCH REPORT

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